



State of California—Health and Human Services Agency  
**Department of Health Services**



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Director

**ARNOLD SCHWARZENEGGER**  
Governor

February 27, 2004

**To:** Chief Executive Officer  
Risk Manager  
Chief of Pediatrics  
Chief of Neonatology  
Chief of Obstetrics  
Chief Nursing Officer  
Perinatal Manager  
NICU Manager  
Laboratory Manager  
Health Information/Medical Records Manager

**Re:** Liability Issues in Newborn Screening

Hospitals incur significant liability if they fail to assure that all newborns born in or transferred to their facilities are screened in accordance with California law. Recently a jury awarded a child with Phenylketonuria (PKU) over \$70 million in damages after finding a hospital and medical clinic negligent for failing to diagnose his disease in the newborn period. The hospital collected the child's newborn screening specimen too early, causing the disorder to go undetected. This letter is to restate the importance of following state newborn screening policies and regulations in order to ensure testing, maximize the reliability of the testing, and minimize the hospital's liability. The following procedures are particularly important in the prevention of missed cases or delayed diagnoses of newborns with a disorder included in the screening program.

***Time of Collection: At discharge, no sooner than 12 hours of age (unless a transfusion is required), or on the 6<sup>th</sup> day of age.***

Based on the large amount of data collected by the Department and from publications in the medical literature, the newborn blood specimen should be collected as close to discharge as possible or for newborns requiring an extended stay on the 6<sup>th</sup> day of age (Title 17, California Code of Regulations, Subchapter 9, Sec. 6505). This means that collections should be scheduled within two hours of discharge. This is especially important if the newborn is discharged before 24 hours of age. Early collection defined as before 12 hours of age runs an unacceptably high risk of missing PKU. If the



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specimen is collected before 12 hours of age, a second specimen must be collected on or before the 6<sup>th</sup> day of age.

### ***Collection Prior to Red Blood Cell Transfusion***

Premature or sick infants frequently receive packed red cell transfusions. The screening specimen should be collected before transfusion, so the presence of galactosemia and hemoglobin disorders can be determined in the absence of confusion produced by foreign adult red cells (Title 17, CCR, Subchapter 9, Sec. 6505). A second specimen should then be collected at least 24 hours post-transfusion to obtain valid results for Phenylketonuria (PKU) and primary congenital hypothyroidism.

### ***IV Feedings***

Intravenous feeding (i.e., hyper alimentation) can also confuse the results of metabolic testing, so testing after intravenous feeding has stopped, if possible, is recommended. However, a specimen should be collected no later than six days of age, regardless of method of feeding (Title 17, CCR, Subchapter 9, Section 6505).

### ***Medical Record Review for Newborn Screening Results***

To ensure testing of newborns, state law mandates that hospitals review all newborns' charts for receipt of newborn screening results (Title 17, CCR, Subchapter 9, Sec. 6506). This should be done 14 days after the newborn has been released from the hospital. For newborns with extended hospital stays this review should occur within 21 days of age. This will help prevent additional delays in diagnosis in situations in which newborns inadvertently did not have a specimen collected as well as when specimens are misplaced or lost in transit between the collection site and the screening laboratory.

### ***Accurately Listing Newborn's Pediatric Care Provider on NBS Test Request Form***

To expedite the follow-up process and to ensure results are sent to the newborn's physician who will be providing ongoing care, it is critical that hospitals identify and accurately note the newborn's primary care provider/medical home on the NBS test request form (Title 17, CCR, Subchapter 9, Sec. 6504)

### ***Newborn Screening is not Diagnostic: Any signs or symptoms should be investigated***

Newborns' physicians need to be reminded that a negative screening result does not eliminate the possibility of the newborn being affected by a disorder in the screen. This is especially true when the results are borderline, i.e., close to positive values. Any

symptoms or signs suggesting a disorder should be immediately investigated by appropriate evaluation and diagnostic testing.

Adherence to the above regulations and guidelines will provide safeguards necessary to assure that all newborns are screened appropriately. The Newborn Screening Program provides information, training, and consultation/technical assistance to hospitals, and other screening providers. Please contact your Newborn Screening Area Service Center (listed below) if you have any questions and/or need assistance.

Sincerely,

*original signed by*

George Cunningham, M.D, M.P.H., Chief  
Genetic Disease Branch

### **Newborn Screening Area Service Centers (NBS-ASCs)**

#### **Stanford University Medical Center (650-812-0353)**

##### **Counties**

<i>Alameda</i>	<i>Mendocino</i>	<i>Santa Clara</i>
<i>Contra Costa</i>	<i>Monterey</i>	<i>Santa Cruz</i>
<i>Del Norte</i>	<i>Napa</i>	<i>Solano</i>
<i>Humboldt</i>	<i>San Benito</i>	<i>Sonoma</i>
<i>Lake</i>	<i>San Francisco</i>	<i>Stanislaus</i>
<i>Marin</i>	<i>San Mateo</i>	

#### **Children's Hospital Central California (559-353-6416)**

##### **Counties**

<i>Alpine</i>	<i>Lassen</i>	<i>Shasta</i>
<i>Amador</i>	<i>Madera</i>	<i>Sierra</i>
<i>Butte</i>	<i>Mariposa</i>	<i>Siskiyou</i>
<i>Calaveras</i>	<i>Merced</i>	<i>Sutter</i>
<i>Colusa</i>	<i>Modoc</i>	<i>Tehama</i>
<i>El Dorado</i>	<i>Mono</i>	<i>Trinity</i>
<i>Fresno</i>	<i>Nevada</i>	<i>Tulare</i>
<i>Glenn</i>	<i>Placer</i>	<i>Tuolumne</i>
<i>Inyo</i>	<i>Plumas</i>	<i>Yolo</i>
<i>Kern</i>	<i>Sacramento</i>	<i>Yuba</i>
<i>King</i>	<i>San Joaquin</i>	

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**Newborn Screening Area Service Centers (NBS-ASCs)**

**UCLA Medical Center (310) 826-4458**

**Counties**

*San Luis Obispo*      *Santa Barbara*      *Ventura*  
Los Angeles  
Antelope Valley Hospital  
Cedars-Sinai Medical Center  
Citrus Valley-Queen of the Valley  
Foothill Presbyterian Hospital  
Glendale Advent Medical Center  
Glendale Memorial Hospital & Health Ctr  
Granada Hills Community Hospital  
Henry Mayo Newhall Memorial Hospital  
Holy Cross Medical Center  
Huntington East Valley Hospital  
Huntington Memorial Hospital  
Medical Center of Tarzana  
Methodist Hospital of Southern Calif.  
Northridge Hospital Medical Center  
Northridge Hosp Med Ctr-Sherman Way  
Olive View Medical Center  
Pacifica Hospital of the Valley  
Pomona Valley Hospital Medical Center  
Queen of Angeles-Hollywood Presbyterian  
Saint John's Health Center  
Saint Joseph Medical Center  
San Dimas Community Hospital  
San Gabriel Valley Medical Center  
Santa Monica – UCLA Medical Center  
Santa Teresita Hospital  
UCLA Medical Center  
Valley Presbyterian Hospital  
Verdugo Hills Hospital  
West Hills Hospital & Medical Center

**UCSD Medical Center (858) 300-1081**

**Counties**

*Imperial*      *Riverside*  
*Orange*      *San Diego*

**Kaiser Permanente Northern CA  
(510) 752-6192**

**Harbor/UCLA Medical Center  
(310) 222-3751**

**Counties**

*San Bernardino*  
Los Angeles  
Bellflower Medical Center  
Bellwood General Hospital  
Beverly Hospital  
California Hospital Medical Center  
Centinela Hospital Medical Center  
Children's Hospital Los Angeles  
Daniel Freeman Memorial Hospital  
Downey Regional Medical Center  
East Los Angeles Community Hospital  
Elastar Community Hospital  
Garfield Medical Center  
Good Samaritan Hospital  
Greater El Monte Hospital  
LAC Harbor-UCLA Medical Center  
LAC/USC Medical Center  
Lakewood Regional Medical Center  
Little Company of Mary Hospital  
Long Beach Memorial Medical Center  
Los Angeles Community Hospital  
Los Angeles Metropolitan Medical Center  
Memorial Hospital of Gardena  
Mission Hospital  
Martin Luther King, Jr. Medical Center  
Monterey Park Hospital  
Pacific Hospital  
Pacific Alliance Medical Center  
Presbyterian Intercommunity Hospital  
San Pedro Peninsula Hospital  
St Francis Hospital  
St Mary Medical Center  
Suburban Medical Center  
Torrance Memorial Hospital  
White Memorial Medical Center  
Whittier Hospital Medical Center

**Kaiser Permanente Southern CA  
(626) 564-3322**